IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter "Ethicon") submit this memorandum in support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D., with respect to the cases set forth in Exhibit A.

INTRODUCTION

Dr. Rosenzweig is a pelvic surgeon and urogynecologist with experience in the surgical treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as the removal of sling systems. Ex. B to Ethicon's Wave 1 Motion, Doc. 2047, curriculum vitae.[1] Dr. Rosenzweig intends to provide general opinions about TVT, TVT-O, TVT-Abbrevo, TVT Exact and TVT Secur (collectively "the TVT Devices"), as well as Prosima. Ex. C-G, Expert Reports. As set forth below, the Court should preclude Dr. Rosenzweig from testifying about matters that are beyond his expertise, that are irrelevant, that are unreliable, that are prejudicial, and/or that would confuse or mislead the jury.

[1] All exhibits cited herein, unless otherwise noted, were filed as exhibits to Ethicon's Wave 1 motion to exclude Dr. Rosenzweig, and maintain the same exhibit label relative to that motion. *See* Doc. 2047. Plaintiffs adopted five different reports attributable just to Dr. Rosenzweig's opinions about TVT and TVT-O *See* Ex. 1-5 to Ex. C. Because most of Dr. Rosenzweig's opinions about the TVT Devices are the same, citations in this brief are generally limited to one of those reports.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Rosenzweig from testifying that other synthetic mesh devices are safer alternatives for the surgical treatment of SUI or POP.

The Court should preclude Dr. Rosenzweig from suggesting that a device with lighter-weight or more macroporous mesh would provide a safer alternative than the devices at issue for the surgical treatment of SUI or POP, because his opinions are unreliable. *See id.* at 33, 52; Ex. C-2, TVT Report No. 2 at 33, 52; Ex. I, Rosenzweig 9/22/15 Dep. Tr. 154:9-155:2. Dr. Rosenzweig specifically claims that Ultrapro is less susceptible to complications than Gynemesh PS and Prolene. *See id.* at 112:8-112:14. This opinion is improper for multiple reasons.

A. Ultrapro has never been available for the treatment of SUI or POP.

Plaintiffs and Dr. Rosenzweig ignore that Ultrapro was never a feasible alternative for the treatment of SUI or POP, because Ethicon was never able to make it commercially available for those usages. Ethicon endeavored to launch a SUI product with Ultrapro mesh, but its cadaver lab tests failed and the FDA rejected Ethicon's 510k application. Ex. B to Ethicon's Wave 1 Reply in support of motion to exclude Dr. Rosenzweig (Doc. 2241), FDA rejection letter; Ex. C to Ethicon's Wave 1 Reply in support of motion to esclude Dr. Rosenzweig (Doc 2241), *Perry v. Luu*, Cal. Superior Ct., No. 1500-cv-279123, Trial Tr. 3293:15-3300:15 (Kern County Fen. 11, 2015). Therefore, Dr. Rosenzweig's sole proposed alternative was, quite simply, never an option.

B. There is no reliable evidence that a device with Ultrapro mesh would have been equally as effective for treating SUI or POP.

Moreover, even if Dr. Rosenzweig could reliably testify that Ultrapro mesh is safer than the mesh in the devices at issue, his opinions are improper because there is no evidence that a

device with Ultrapro mesh would be equally as efficacious for the treatment of SUI or POP. In denying Ethicon's motion to preclude Dr. Rosenzweig from offering these opinions in *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016), the Court reasoned, in part, as follows:

> Ethicon first argues that this testimony is based on a logical fallacy—the logical fallacy being that a device that results in fewer complications is a safer alternative design. I see no logical fallacy here; whether an alternative device has few complications is surely related to whether the alternative is safer.

Even if an alternative device would lead to fewer complications, the alternative device is not a *feasible* alternative device (although safer) if the alternative would not be as effective as the device at issue for the treatment of a medical condition. *See, e.g., Conklin v. Novartis Pharm. Corp.*, 2012 U.S. Dist. LEXIS 136428, at *26-27 (E.D. Tex. Sept. 18, 2012). A placebo, for instance, would nearly always provide a safer alternative to any drug, but it could not serve as a feasible safer alternative because it is not as effective for treating disease. Because neither Dr. Rosenzweig *nor any other expert* can identify any reliable studies demonstrating that Ultrapro or some other mesh device is as *efficacious* as Ethicon's devices for the surgical treatment of SUI or POP, Dr. Rosenzweig's vague opinions are inadmissible.

Moreover, Dr. Rosenzweig has conceded that there is insufficient long-term data to measure Ultrapro's safety and efficacy. Ex. I, Rosenzweig 9/22/15 Dep. Tr. at 185:16-20. According to Dr. Rosenzweig, "I would like to see more data on Ultrapro," "I don't think we have enough information" about Ultrapro, and "I don't think it has been studied long enough." Ex. K, Rosenzweig 7/13/15 Dep. Tr. 174:13-17, 198:8-13. In fact, Dr. Rosenzweig has acknowledged his uncertainty about the feasibility of Ultrapro given the lack of research concerning its use in the treatment of SUI:

> I used Ultrapro as an example since that is an example that is on the market. Obviously in order to justify the use of a polypropylene-based product like Ultrapro, there would have to be a significant amount of research to be able to make sure that the amount of polypropylene that's leftover in Ultrapro, it is large -- a lighter weight, larger pore, smaller filament size is "biocompatible" with tissue.
>
> If you look at a single suture of polypropylene, that is probably below the minimal amount of polypropylene that is biocompatible with the body, just like when you look at flu vaccines, a flu vaccine has heavy metals in it, such as mercury and others. There is a minimal amount of -- of things like heavy metals and other toxic substances that is still biocompatible, even though at higher levels it becomes bioincompatible.
>
> And, so, therefore, there would need to be a significant amount of research to look at the -- whether the amount of polypropylene in Ultrapro is still at the level of biocompatibility. The research does seem to show that it is, as we've talked about before in other depositions, but that would also need to have, you know, a significant amount of research to be able to say if that is the case.

Ex. I, Rosenzweig 9/22/15 Dep. Tr. 180:17-181:18. Dr. Rosenzweig may not equivocally suggest that Ultrapro offers a feasible safer alternative while simultaneously stating that it has not been subjected to sufficient studies.[2]

II. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

The Court also should preclude Dr. Rosenzweig from suggesting that laser-cut TVT mesh is a safer alternative to mechanically-cut TVT mesh, or vice versa. In his TVT and TVT-O reports, Dr. Rosenzweig opines that fraying, roping, curling, and other deformities are associated with mechanically-cut mesh and posits that laser cutting was a viable solution to correct the

[2] Only one study to date—the "Okulu study"—has examined the use of Ultrapro in the treatment of SUI. *See* Ex. I, Rosenzweig 9/22/15 Dep. Tr. 174:20-177:2. The Okulu study did *not* compare Ultrapro (or any of the other lighter-weight, larger-pore meshes) to TVT. *See id.* at 114:22-114:25. In fact, the Okulu study involved a different and more invasive type of surgery—one that did not employ the TVT retropubic procedure. *See id.* at 115:1–117:8. Moreover, whereas TVT surgery is an outpatient procedure, the patients in the Okulu study spent an average of two days each in the hospital. *See* Ex. J, Okulu, E., Kayigil, O., Aldemir, M. & Onen, E., *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, SCAND. J. UROL., 47:217-224, 220 (2013).

fraying, roping, and curling issue. Ex. C-2, TVT Report No. 2 at 41-48. At the same time, however, Dr. Rosenzweig criticizes laser-cut mesh in his TVT-Exact and TVT-Abbrevo and suggests that mechanically-cut mesh is preferable. Ex. D, TVT-Abbrevo Report at 12-13; Ex. E, TVT-Exact Report at 12-13.

A. Dr. Rosenzweig's opinions are unreliably inconsistent.

Dr. Rosenzweig may not suggest that one type of cut of mesh is a feasible, safer alternative if he is unwilling to stand behind that product. He has not done so. Dr. Rosenzweig cannot have it both ways and simultaneously argue that mechanically-cut mesh is less safe than laser cut-mesh and that laser-cut mesh is less safe than mechanically-cut mesh. If the Court permits Dr. Rosenzweig to offer opinion testimony critiquing mechanically-cut mesh, it should preclude him from referencing laser-cut mesh as a viable alternative design, and vice versa. *See Huskey*, 29 F. Supp. 3d at 712 (precluding expert from testifying that laser-cut mesh was preferable given vague, noncommittal testimony).

B. Dr. Rosenzweig's opinions are unreliable.

Further, Dr. Rosenzweig's opinions lack a reliable, scientific foundation. Dr. Rosenzweig cites *no* studies in support of his opinions about complications attributable to mechanically-cut mesh. *See* Ex. I, 9/22/15 Rosenzweig Dep. Tr. at 198:18-204:12; *see also id.* at 201:22-202:14. He admits that he knows of no clinical data showing that mechanically-cut TVT mesh is associated with a statistically significantly higher rate of pain or dyspareunia than laser-cut TVT mesh. *See id.* at 201:6-203:2. In fact, he testified that "the only study that directly compared laser cut mesh with mechanical cut mesh showed *a higher rate of erosion in the laser cut mesh*." *Id.* at 200:23-201:5 (emphasis added). In *In re AlloDerm Litig.*, the New Jersey court found that the alternative design requirement was not met when the proposed alternative design

was not shown to be safer and feasible through testing or literature. *See* Ex. L (*Alloderm* Design Defect Order) at 29-32.

Further, from a clinical standpoint, Dr. Rosenzweig has no knowledge of ever implanting a patient with laser cut mesh. *See* Ex. Q, Rosenzweig 3/24/14 Dep. Tr. 174:13-22, 176:20-24. Thus, he lacks the ability to opine based on "experience" that there is a difference in outcome regarding the two.

Recently in *In re Ethicon*, 2016 WL 4500765, at *3, the Court reserved ruling on the reliability of Dr. Rosenzweig's mesh-cut opinions until further information could be provided about Dr. Rosenzweig's clinical experience. Here, the Court may find at this juncture that Dr. Rosenzweig lacks the requisite clinical experience to provide reliable testimony given his concession that he does not believe that he has ever implanted any of his patients with laser-cut mesh. Ex. Q, Rosenzweig 3/24/14 Dep. Tr. 174:13-22, 176:20-24. It is impossible for Dr. Rosenzweig to provide a reliable comparison of laser-cut mesh and mechanically-cut mesh based on his personal clinical experiences if he has never implanted laser-cut mesh.

III. The Court should limit Dr. Rosenzweig's product warning opinions.

Dr. Rosenzweig claims that Ethicon failed to provide adequate warnings to physicians and patients about the purported risks associated with the devices at issue. *See* Ex. C-1, TVT Report No. 1 at 20-24, 53-72, 76, 81-97; Ex. G, Prosima Report at 45-50. Because Dr. Rosenzweig is not qualified to offer such opinions, the Court should limit Dr. Rosenzweig's testimony regarding warnings.

This Court has found that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about

what information should or should not be included in an IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582220, at *3 (S.D. W. Va. Sept. 1, 2016). Defendants acknowledge that the Court has previously determined that Dr. Rosenzweig has sufficient expertise to criticize Ethicon's IFUs because he provided unspecified consulting for a company that drafted an IFU. *See Huskey*, 29 F. Supp. 3d at 704. Defendants, however, respectfully request that the Court revisit that ruling in this wave of cases.

Although Dr. Rosenzweig claims he is a warnings expert (*see* Ex. R, Rosenzweig 11/4/13 Dep. 223:8), Dr. Rosenzweig believes that any doctor who uses a medical device with an IFU qualifies as an expert on IFUs:

> I think that doctors have -- that are using the IFU, using it to decide if they are going to keep it in their -- use a device in their practice to determine if an individual patient that device is useful for and then counseling the patient on the use of that device, the risks and benefits associated with it, I would say that that would qualify them as an expert in IFUs.

Id. at 285:25-286:7. Yet, Dr. Rosenzweig has conceded that he has never drafted an IFU (*id*. at 53:24-25), has never prepared risk management reports (*id.* at 54:25-55:7), has never been employed with or served as a consultant for the FDA, and has never served on an FDA advisory committee. *Id*. at 55:10-15.

This Court has determined that other pelvic surgeons with credentials similar to those of Dr. Rosenzweig are not qualified to criticize IFUs. *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582220, at *3 (S.D. W. Va. Sept. 1, 2016) (excluding Dr. Bobby Shull); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016) (excluding Dr. Michael Margolis); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, at *4 (S.D. W. Va. Aug. 26, 2016)

(excluding Dr. Jerry Blaivas). Consistent with those rulings, the Court should allow Dr. Rosenzweig to testify about whether specific risks appear on the IFUs but preclude him from testifying "what information should or should not be included in an IFU." *Id.*

IV. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

Although he has no experience as a biomaterials expert or a polymer scientist (Ex. H, 11/4/13 Dep. Tr. 56:13-23), Dr. Rosenzweig makes a number of assertions about biomaterials opinions that are unreliable, irrelevant, and/or otherwise improper. The Court should preclude Dr. Rosenzweig from testifying about degradation and cytotoxicity, because neither Dr. Rosenzweig nor any other expert can reliably show that these alleged events have caused any women to sustain any clinically adverse events.

The Court recently rejected a similar argument in adjudicating Ethicon's Wave 1 challenge of Dr. Rosenzweig. *In re: Ethicon*, 2016 WL 4500765, at *4. Although the Court implicitly found that Dr. Rosenzweig's testimony did not establish a link between these alleged mesh characteristics and any clinically adverse impact, the Court reasoned that "[a] *single expert* need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case." *Id.* (emphasis added). Here, however, Plaintiffs do not have another expert who can complete the missing pieces of the puzzle. Without the last piece of the puzzle, Dr. Rosenzweig's testimony is irrelevant and confusing to the jury.

Further, the Court recently excluded Dr. Daniel Elliott's opinions related to mesh properties, because he similarly could not link these properties to clinical harm. *In re: Ethicon*, 2016 WL 4500768, at *3. For these same reasons, the Court should exclude Dr. Rosenzweig's biomaterials opinions in this wave of cases. The specific deficiencies in Dr. Rosenzweig's testimony are discussed in greater detail below.

A. Degradation

The Court should exclude Dr. Rosenzweig's general opinion that Ethicon's devices at issue are defective because their mesh supposedly degrades *in vivo* and is subject to fraying and particle loss. *See* Ex. C-2, TVT Report No. 2, pp. 13-22, 36-48; Ex. G, Prosima Report, pp. 14-22. Dr. Rosenzweig's opinion is unreliable because neither he nor any of Plaintiffs' other experts can connect the alleged degradation, fraying, and particle loss to adverse events experienced by women.

In *Huskey*, the Court allowed Dr. Rosenzweig to testify about these topics. 29 F. Supp. 3d at 707-09. Subsequent to that decision, however, Dr. Rosenzweig has admitted that there are no studies connecting degradation, fraying, or particle loss to an adverse event. *See* Ex. I, 9/22/15 Rosenzweig Dep. Tr. at 251:18-256:4. The best that he can come up with is a case report where mesh was explanted and allegedly showed degradation, fraying, or particle loss. *See id.* That does not constitute reliable evidence of causation, however. *See, e.g.*, *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 n.5 (8th Cir. 2000) ("Case reports are generally not considered reliable evidence of causation.") (collecting cases); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003) ("The great weight of authority—and the most current authority—squarely rejects the use of . . . case reports for the purpose of establishing general causation.").

Dr. Rosenzweig's opinion about degradation is premised on an improper *post hoc ergo propter hoc* logical fallacy. Dr. Rosenzweig takes two premises—(1) Prolene and Gynemesh PS mesh are subject to degradation, fraying, and particle loss, and (2) women complain of pain following the implantation of Ethicon's devices—and he then attempts to connect the two events, suggesting that *because* mesh allegedly degrades, frays, and loses particles, women implanted with the mesh must experience pain. That is, Dr. Rosenzweig impermissibly assumes the

existence of a causal connection between his two posited premises. Because neither Dr. Rosenzweig nor anyone else can reliably show that alleged degradation causes adverse effects in women, his opinions should be excluded.

B. Cytotoxicity

In reports, Dr. Rosenzweig opines that Ethicon did not act as a reasonable medical device manufacturer because it failed to inform physicians and their patients about the "potential for cytotoxicity or cell death." Ex. C-1, TVT Report No. 1, p. 65; Ex. G, Prosima Report, pp. 14, 17, 27. The Court should preclude Dr. Rosenzweig, who has never performed any cytotoxicity testing of polypropylene (Ex. H, Rosenzweig 11/4/13 Dep. Tr. 222:4-6), from testifying that polypropylene mesh is cytotoxic or that Ethicon should have warned physicians of toxicity testing.

In *Huskey*, the Court allowed Dr. Rosenzweig to testify about cytotoxicity. 29 F. Supp. 3d at 705. Subsequent to that ruling, however, Dr. Rosenzweig has admitted that there are no clinical studies reporting that any alleged Prolene cytotoxicity causes any complications in women. *See* Ex. I, Rosenzweig 9/22/15 Dep. Tr. 256:5-257:14. When asked during his deposition if he was "aware of any studies that report for Prosima or Gynemesh PS in women that complications were deemed to be due to cytoxicity," Dr. Rosenzweig responded: "Not that I recall." Ex. K, Rosenzweig 7/13/15 Dep. Tr. 195:16-20. He also testified that "I can't tell you what the general consensus is" within the medical field about whether the mesh is cytotoxic. *Id.* at 208:23-209:8. As with his opinions about degradation, Dr. Rosenzweig's opinions about cytotoxicity are deficient because neither he nor anyone else can reliably link alleged cytotoxicity with clinical harm.

V. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

Dr. Rosenzweig makes a number of opinions about duties allegedly owed by Ethicon as a medical device manufacturer that are well outside of Dr. Rosenzweig's expertise. Dr. Rosenzweig is not qualified to provide such testimony, and his opinions are unreliable.

A. Testing

Dr. Rosenzweig suggests that Ethicon did not perform adequate testing and studies. *See, e.g.*, Ex. C-1, TVT Report No. 1, pp. 61-65; Ex. G, Prosima Report, pp. 18-21, 36. In fact, the TVT is one of the most-tested medical devices ever made. In precluding Dr. Rosenzweig from offering similar testimony, this Court found that "[t]here is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon*, 2016 WL 4500765, at *5; *Huskey*, 29 F. Supp. 3d at 705. Dr. Rosenzweig has gained no additional expertise, and accordingly, the same reasoning continues to apply.

B. Adverse Event Reporting

For similar reasons, this Court also should exclude Dr. Rosenzweig's opinion that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading." Ex. C-2, TVT Report No. 2, p. 97. Dr. Rosenzweig's experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g.*, *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting

because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

Not surprisingly, because Dr. Rosenzweig has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to collect and report adverse events in the manner he suggests it should have. In fact, Dr. Rosenzweig does not identify *any* basis or reason for his opinion, as he must. Instead, his opinion is apparently based purely on personal belief. The Court should exclude his opinion on that basis. *See Hines v. Wyeth*, 2011 WL 2680842, *5 (S.D. W. Va. July 8, 2011) (finding that expert provided no basis for opinions, rendering them inadmissible "personal opinion").

Dr. Rosenzweig's critique of Ethicon's adverse event reporting amounts to nothing more than a narrative summary of the evidence. Dr. Rosenzweig cites or quotes Ethicon e-mails and company witness depositions purporting to show that Ethicon employees did not know how many complaints were missed by the company's "complaint tracking system." Because the jury does not need an expert witness to read documents and summarize evidence, the Court should exclude Dr. Rosenzweig's opinions regarding adverse event reporting. *See, e.g.*, *Hines*, 2011 WL 2680842, at *7 (excluding as "irrelevant" and "unhelpful" expert opinion "based on [the expert's] own reading of defendants' internal documents" that the "jury is more than capable of reading and summarizing"); *In re: Ethicon,* 2016 WL 4500765, at *7 ("caution[ing] the parties against introducing corporate evidence through expert witnesses").

C. Training

Dr. Rosenzweig claims that Ethicon did not fund and provide appropriate training to physicians concerning the use of TVT-O and TVT-Abbrevo. Ex. C-4, TVT-O Report No. 4, pp. 74-77; Ex. D, TVT-Abbrevo Report, pp. 73-77. Dr. Rosenzweig is not qualified to testify about what funding and level of training that a medical device manufacturer should provide. Further, his

opinions are based on a narrative summary of documents rather than any special expertise. In addition, Dr. Rosenzweig's opinions are irrelevant and prejudicial insofar as he does not claim that a specific Plaintiff's implanting physician was not appropriately trained or competent. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances).

VI. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT-Abbrevo.

In his TVT-Abbrevo report, Dr. Rosenzweig states that "the shorter length of the laser cut mesh in the TVT Abbrevo leads to more complications." Ex. D, TVT-Abbrevo Report at 13. Dr. Rosenzweig cites no studies in support of his conclusory statement. It appears that it is based solely on one internal Ethicon document, which lends no support to the statement. Ex.P, ETH.MESH.09911296. As in *In re: Ethicon*, 2016 WL 4500765, at *5, the Court should exclude this opinion as unreliable.

VII. The Court should exclude Dr. Rosenzweig's marketing opinions.

Dr. Rosenzweig criticizes Ethicon for marketing TVT Devices to women who are obese, elderly, young and active, or with "certain pre-existing conditions." Ex. C-1, TVT Report No. 1, pp. 82-86. In his Prosima report, Dr. Rosenzweig states that "certain patient populations were more likely to experience adverse outcomes" from the device, but he bases his opinions on Prolift, rather than Prosima, and he does not identify the specific types of patient populations. Ex. G, Prosima Report, p. 50. To the extent that Dr. Rosenzweig intends to testify about patient populations of which each respective Plaintiff is not a member, any such testimony is irrelevant and unhelpful to the jury and therefore inadmissible. *See* Fed. R. Evid. 402, 702.

As in *In re: Ethicon*, 2016 WL 4500765, at *6, and other cases, the Court should exclude such opinions because Dr. Rosenzweig's opinions are based on a narrative summary of Ethicon documents.

VIII. The Court should preclude Dr. Rosenzweig from testifying about MSDS sheets.

According to Dr. Rosenzweig, Ethicon's mesh at issue should not be used in the vagina on the basis of the mesh MSDS sheet, which suggests that it is incompatible with "strong oxidizers" such as chlorine and nitric acid. Ex. C-1, TVT Report No. 1, pp. 61-64; Ex. G, Prosima Report, pp. 35-39. Although the Court has previously rejected Ethicon's challenge to Dr. Rosenzweig discussing the MSDS sheet, *see In re: Ethicon*, 2016 WL 4500765, at *4, Ethicon respectfully submits that Dr. Rosenzweig is not qualified to offer opinions about the MSDS and that any such opinions would be unreliable and prejudicial.

Issues about biomaterials properties and a MSDS are well beyond Dr. Rosenzweig's qualifications as a urogynecologist, and he does not know how the MSDS was generated. An MSDS is hearsay and cannot come into evidence through an expert if the expert does not know how the statements on the MSDS were prepared. *See Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (suggesting expert's ignorance of the tests utilized to formulate MSDS diminished reliability of MSDS); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (same); *Ingram v. Solkatronic Chem., Inc.*, 2005 U.S. Dist. LEXIS 38304, at *22-23 (N.D. Okla. Dec. 28, 2005) (citing *Turner* and *Moore* and excluding expert opinion under *Daubert* where expert opinion largely based on information in MSDS, but expert had no knowledge of how the MSDS was generated).

Further, while the MSDS states that the raw polypropylene to which it applies is incompatible with "strong oxidizers," that statement is irrelevant because several antioxidants are added to the raw polypropylene in the process of manufacturing the Prolene used to make Ethicon's products at issue. Ex. O, ETH.MESH.02026591. In fact, as a matter of law, the

MSDS only applies to raw chemicals and not to finished medical devices regulated by the FDA. *See* 29 C.F.R. § 1910.1200(b)(5)(iii).

Allowing testimony about the MSDS would be especially irrelevant and prejudicial given the lack of scientific testing to show that any oxidation or degradation (allegedly found on a layer one micron thick and visible only under an electron microscope) causes any clinical harm.

IX. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Consistent with the Court's prior rulings, the Court should also preclude Dr. Rosenzweig from: (a) speculating about Ethicon's alleged knowledge and corporate conduct;[3] (b) discussing cancer and other complications that a respective Plaintiff has not had and that no competent physician has testified that the Plaintiff likely will sustain;[4] (c) offering legal conclusions;[5] and (d) providing a narrative summary of Ethicon documents.[6] *See, e.g., In re: Ethicon*, 2016 WL 4500765, at *7; *In re: Ethicon*, 4500767, at *5.

[3] *See, e.g.*, Ex. C-2, TVT Report No. 2, pp. 2, 30, 39, 43, 48, 49, 61, 68, 70, 72, 75, 76, 80.
[4] *See id.* at 78-83.
[5] *See id.* at 28, 72, 77, 84-85.
[6] *See, e.g.*, Ex. C-1, TVT Report No. 1, pp. 32-35, 39-61.

CONCLUSION

For the reasons set forth and referenced herein, Defendants respectfully request that the Court grant their Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

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IN THE UNITED STATES DISTRICT COURT
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I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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